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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,230

06/21/2005

David L. Reynolds

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EXAMINER

WIEST, PHILIP R

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,230	Applicant(s) REYNOLDS, DAVID L.	
	Examiner Phil Wiest	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-24 and 29-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-24 and 29-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. In the reply filed 7/7/08, applicant amended claims 1 and 29 and added new claims 30-45. Claims 1-9, 11-24 and 29-45 are currently pending.

Response to Arguments

2. Applicant's arguments filed 7/7/08 have been fully considered but they are not persuasive. Applicant argues that the prior art of record does not teach or suggest the claimed device.

3. Regarding the Rejection of Claim 1 in view of Genese, Applicant argues that Genese does not teach the device as claimed for a variety of reason. Specifically, applicant states that Genese does not teach that the housing is connected to a piston. This argument has not been found persuasive because housing 10 is clearly connected to piston 31 by internal and external threads (38 and 40, see Figure 2). It is important to note that the housing may be any part of the outer structure of the device, and applicant does not specifically claim which part of the housing the piston is connectable to. Applicant also argues that Genese does not teach a vial socket for receiving and engaging the neck of a vial. This has not been found persuasive. The examiner has interpreted the "engaging the neck" of a vial to mean that the side walls of the vial are held by the vial socket. Genese clearly teaches that the side walls vial 18 are engaged by a vial socket (defined by walls 11 and 17).

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4. Applicant also argues that the function of the Genese device is different because it is designed to transfer fluid from a first container to a second container, and back to the first container. This is merely the intended use of the system. Genese's vial adapter is fully capable of being used in the same manner as the claimed device.

5. Regarding Claim 21, applicant argues that the Genese does not teach that the vessel is a cartridge having a penetrable seal and a cap. This argument has not been found persuasive. A cartridge may be any shape. The sidewalls of the vessel define a neck portion that has a penetrable seal 60 therethrough. The phrase "a cap to retain the penetrable closure thereon" is functional language and therefore has not been given patentable weight. The extended arm portion of the housing (36, 37) defines a cap portion.

6. Regarding the rejection of Claims 1-4, 9,11-13, 21, and 29 over Haber in view of Genese, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Genese clearly suggests the use of a slidable piston in order to create a seal that simultaneously seals the vessel and allows the vessel to be punctured when moved from a first position to a second position.

7. Applicant's arguments state that both Haber and Genese are "so remote from the teachings of Applicant that it is not seen where any such combination is practical or operable." Haber and Genese, as well as applicant's claimed device, are drawn to vial adapters for transferring fluids from one container to another container in a sterile manner. It is the examiner's opinion that one of ordinary skill in the art would have been motivated to apply Genese's piston-based hub system to Haber's device in order to create a well known, alternate means for transferring medical fluids from one chamber to another.

8. Applicant also argues that Haber does not teach a socket assembly for receiving the vial. However, it is clear that the vial is inserted into a socket assembly defined by wall 58 (see Figure 4). The examiner concedes that reference numeral 48 was cited by mistake. At the time of the previous office action, it was thought that numeral '48' corresponded to the vertical wall opposite wall 58. Regardless, it is abundantly clear from the figures that the structure defined by cylindrical wall 58 is a cylindrical vial socket for receiving a vial. Additionally, Applicant argues that the bore 92 of Haber functions differently than the claimed device. However, this argument is related to the *function* of the bore, not the *structure*.

9. Regarding Claim 9, Applicant argues that Haber does not disclose an aperture on the side wall of the conduit having a blunt end. However, Haber clearly teaches an aperture 136 disposed on the side wall of the conduit. The aperture 136 has a substantially blunt end, as do both of the conduits adjacent the aperture. See Figure 7.

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10. With respect to Claims 11-13, Applicant argues that Haber does not teach a retaining member having retaining latches. A latch may be any structure that substantially holds an object in place. The retaining means 40 and their angled inner walls are fully capable of holding the vial in place, and therefore function as latches.

11. With respect to Claim 21, Applicant argues that Haber does not teach that the vessel is a cartridge having a neck with a penetrable closure and a cap thereon.

However, Figure 7 clearly shows a vessel 10 having a neck with a penetrable closure. Additionally, the penetrable closure is clearly covered by a cap, as is well known in the art.

12. Applicant also traverses the rejections of claims 7, 8, 14, and 15-24 based on alleged deficiencies in the Haber and Genese patents. Based on the responses provided by the Examiner above, this argument is moot.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1, 2, 11, 14, 21, 29, 30, 37, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Genese (US 4,180,070).

15. With respect to Claims 1 and 29, Genese discloses an assembly for transferring fluid between a vessel 42 having a piston 31 and a vial 18 comprising a housing 10

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having first and second ends and a bore 45 extending therethrough, the piston being removably connected to the housing. A conduit 23 having first and second apertures is longitudinally slidable within the bore between a retracted position (Figure 1) and an activated position (Figure 2). The device further comprises a vial socket assembly (11, 17) having a vial socket (within aperture 14) for receiving a vial, and a hollow piercing member (at piercing point 24) for piercing the vial, said vial socket assembly moveable longitudinally relative to the housing with the housing. The second end of the conduit is fully capable of being releasably connected to the vial socket assembly. Advancing the vial socket assembly longitudinally toward the housing advances the conduit from the retracted position to the activated position to fluidly connect the vessel and the vial. See Figures 1-3.

16. With respect to Claims 2, 11, 14, 21, 30, 37, and 39, the first end of the conduit has a piercing member and the conduit has an aperture at the tip that extends through the conduit. The interior of the vial socket is a retaining member. The vessel 42 may be a syringe or a cartridge. The sidewalls of the vessel define a neck portion that has a penetrable seal 60 therethrough. The extended arm portion of the housing (36, 37) defines a cap portion.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 1-4, 9, 11-13, 21, 29-32, 37, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al. (US 5,393,497) in view of Genese.

19. With respect to Claims 1 and 29, Haber discloses an assembly for transferring fluid between a vessel and a vial comprising a housing 2 having first and second ends and a bore (22, 90) extending therethrough, and a slidable piston (between spaces 90 and 104 in Figure 3) removably connected to the housing. A conduit (110, 53) having first and second apertures is longitudinally slidable within the bore between a retracted position in which the first aperture (above the piston in figure 3) is positioned within the housing and connected to the piston, and an activated position in which the first aperture protrudes into the body of a vessel 10 that is attached to the housing. The device further comprises a vial socket assembly (48, 58) having a vial socket (48, 58) for receiving a vial, and a hollow piercing member 53 for piercing the vial, said vial socket assembly moveable longitudinally relative to the housing with the housing. The second end of the conduit is releasably connected to the vial socket assembly. Advancing the vial socket assembly longitudinally toward the housing advances the conduit from the retracted position to the activated position to fluidly connect the vessel and the vial. Haber, however, does not specifically disclose that the slidable piston is located within the vessel.

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Genese discloses a fluid transfer assembly for transferring fluids between a vessel and a vial comprising a vessel 42 having a piston 31 disposed therein. The vessel and piston are capable of moving relative to the assembly, thereby allowing the conduit to puncture the piston and create fluid communication between the vessel and the vial. By locating the piston within the vessel, it creates a seal, thereby preventing fluids from exiting the vessel except through the conduit (see Figures 1-3). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the transfer device of Haber with the piston enclosed in the vessel of Genese in order to provide a sealing means that allows fluid to be transferred through the conduit when the device is advanced to the second position.

20. With respect to Claims 2, 3, 30, and 31, the first end of the conduit has a piercing member that pierces the vessel, and the aperture is an opening adjacent the tip of the piercing member. A plurality of hubs are also disposed in the housing:

23. With respect to Claims 11-13, 37, and 38, the vial socket assembly 58 comprises a retaining member (30, 60) in the vial socket for retaining a vial 8 within the vial socket. The retaining member further comprises a plurality of retaining latches (40, 44). The retaining member 30 gets narrower near the top (above the retaining latches (40, 44), therefore forming an annular ridge with a smaller inner diameter than the surrounding area.

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24. With respect to Claim 21, Haber discloses that the vessel is a cartridge (a “cartridge” may be of any shape) having a neck with a penetrable closure and a cap to retain the closure thereon.

25. Claims 4-6, 14, 32-34, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Genese, and further in view of Safabash (US 6,253,804).

26. With respect to Claims 4-6 and 32-34, Haber and Genese disclose the device substantially as claimed (see rejection above), and further disclose that the bore of the housing has a first portion, a second portion, and a shoulder disposed therebetween. Haber and Genese, however, do not specifically disclose that the post and hub form a luer connector. Safabash discloses a fluid transfer container system comprising a first container, a second container, and a piston hub 10 disposed therebetween (see figure 1). The containers may be connected to the hub by luer connectors 74 (see Figure 11) to ensure a safe, secure fit (Column 7, Lines 35-39). Luer connectors are extremely well known in the medical fluid transfer art for this very reason. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid transfer system of Haber in view of Genese with the Luer connector of Safabash in order to improve the quality of the seal between containers during medical fluid transfer, thereby ensuring sterility of the fluid.

27. With respect to Claims 14 and 39, Haber and Genese disclose the device substantially as claimed, but do not specifically claim that the vessel is a syringe. Safabash discloses a fluid transfer device comprising a syringe that is attached to a

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piston hub 10. The syringe comprises a neck 34 with a flanged head portion disposed thereon. Furthermore, the syringe is positioned such that capable of being pierced by a needle to establish fluid communication. This type of fluid transfer is well established in the art. Therefore, it would have been obvious to one of ordinary skill in the art to replace the first vessel of Haber in view of Genese with a syringe in order to allow for fluid transfer from a different type of container. Additionally, the use of a syringe allows for control (via the piston 40) over the rate at which fluid is dispensed.

28. Claims 7, 8, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Genese and Safabash, and further in view of Haining (US 5,527,306). Haber, Genese, and Safabash disclose the device substantially as claimed (see rejection above), but do not specifically disclose the use of springs as a biasing members for the conduit. Haining discloses a vial adapter comprising a spring that surrounds a valve stem and provides an upward force to bias the seat from an open to a closed position (Column 2, Lines 61-67). Springs provide an inexpensive, effective biasing member for improving the functionality of moving parts of a fluid flow device. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Haber, Genese, and Safabash with the resilient biasing spring of Haining in order to cause the device to return to the retracted position quickly and easily, thereby reducing the amount of effort required to operate the device.

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29. Claims 15-24 and 40-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Genese and Safabash, and further in view of Koller (US 2004/0260248). Haber, Genese, and Safabash disclose the device of claim 14 substantially as claimed, but do not disclose that the device further comprises a piston backstop device. Koller discloses a medicinal syringe having a piston stopper means that is shaped and sized to receive a housing, and removably connected to the flange of the syringe. Piston backstops are well established in the art of medical fluid transfer devices because they prevent unintentional withdraw of the piston element from the bore and prevent the device from being reused [0027]. Therefore, it would have been obvious to one of ordinary skill in the art to modify the fluid transfer device of Haber, Genese, and Safabash with the piston stopper of Koller in order to prevent the piston element from being removed from the bore, and to prevent the device from being reused.

30. With respect to Claim 18, Haber discloses that the vessel is a glass container. Glass syringes are also well established in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute a plastic syringe for a glass syringe because the selection of a known material based on its suitability for its intended use does not constitute a patentable improvement over the prior art. See MPEP § 2144.07.

31. With respect to Claims 20, 24, and 44, Haber in view of Genese and Safabash and Koller disclose the device substantially as claimed, but do not specifically disclose that the piston backstop is integrally molded to the vessel. However, the use of a one-

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piece construction instead of the structure disclosed in the prior art would merely a matter of obvious engineering choice. See MPEP § 2144.04. Therefore, it would have been within the scope of one of ordinary skill in the art at the time of invention to integrate the vessel and the piston backstop in order to simplify the device and prevent reuse of the fluid transfer device. Additionally, the devices of Haber and Genese are fully capable of being used with a plastic vessel. Plastic vessels are extremely common in the art of medical fluid handling.

Conclusion

32. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

//Leslie R. Deak//
Primary Examiner, Art Unit 3761
10 November 2008